United States Court of Appeals

for the Second Circuit

APPELLEE'S BRIEF

Original w/ affidavit of mailing

3/15

75-6109

To be argued by
CYRIL HYMAN

B
P/S

United States Court of Appeals

FOR THE SECOND CIRCUIT

Docket No. 75-6109

ELIZABETH DALEY, M.D.,

Plaintiff-Appellant,

—against—

F. DAVID MATHEWS, Secretary of Health, Education and Welfare, ALEXANDER M. SCHMIDT, M.D., Commissioner of Food and Drugs, CLIFFORD G. SHANE, Regional Director of the Food and Drug Administration, TERRY MUSSON, ALLEN R. HALPER, JOHN E. KLEMMER and THOMAS D. GARDINE, Employees of the Food and Drug Administration,

Defendants-Appellees.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

BRIEF FOR DEFENDANTS-APPELLEES

DAVID G. TRAGER,
United States Attorney,
Eastern District of

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BRIEF FOR DEFENDANTS-APPELLEES

Counterstatement of the Issues Presented

1. Whether the district court erred in holding that a controversy sufficiently ripe for adjudication does not presently exist between the parties.

2. Whether this is a proper case for the exercise of the Court's discretion to grant a declaratory judgment.

3. Whether there is any basis for injunctive relief.

4. Whether the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 374, authorizes inspection by the Food and Drug Administration of the premises of a physician's office.

A. Preliminary Statement

This is an appeal from an order of the district court (Neaher, *J.*) granting defendants' motion for summary judgment and dismissing the complaint on the ground that a controversy sufficiently ripe for adjudication does not presently exist between the parties (A-52).[1] The court's memorandum opinion and order appears at 400 F. Supp. 1288. The complaint sought declaratory and injunctive relief against Secretary Mathews[2] and other defendants who are employed in New York by the United States Food and Drug Administration (FDA).

B. Statement of Facts

In September 1974 FDA received a report indicating that plaintiff had received or was receiving shipments of a dangerous and illegal drug known as Liefcort for use in the treatment of patients. See affidavit of FDA official Paul J. Sage (A-38-39). As that affidavit indicates, FDA files show that the drug Liefcort is an irrational mixture of potent hormones and that very serious adverse effects have been attributed to the use of the drug.

A preliminary investigation by FDA's New York District Office indicated that plaintiff was distributing the drug involved whereupon a formal inspection of plaintiff's premises was ordered. See affidavit of FDA official George J. Gerstenberg (A-30-31) and the affidavit of

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[1] References preceded by the letter "A" are to appellant's Appendix.

[2] Pursuant to Rule 25(d) of the Federal Rules of Civil Procedure, F. David Mathews has been substituted as the defendant Secretary of Health, Education, and Welfare.

Supervisory Consumer Safety Officer Terry B. Musson (A-22-24).

On February 10, 1975, Consumer Safety Officer Allen R. Halper visited the office of plaintiff, presented an official notice of inspection (A-12) to a nurse who was present at the premises, and explained the purpose of his visit. The nurse advised investigator Halper that Dr. Daley had hours on Wednesday and Thursday from 10:00 a.m. until 4:00 p.m. and that she would not provide any information with regard to plaintiff's operations or any related information. The nurse further indicated that all information with respect to Dr. Daley would have to be obtained from her lawyers, Rothblatt, Seijas, and Peskin. The nurse stated also that even if Dr. Daley were visited during her office hours the investigator would be referred to her lawyers.

Thereafter, another inspection was planned for a day on which the nurse indicated Dr. Daley maintained office hours. See affidavit of Supervisory Consumer Safety Officer, Terry B. Musson (A-22-24). On February 27, 1975, a Thursday, Consumer Safety Officers John E. Klemmer and Thomas D. Gardine, visited plaintiff's office for the purpose of attempting to conduct an inspection. They arrived at Dr. Daley's office at approximately 10:30 a.m. on February 27 and found the door to the office locked. When they rang the bell outside the door, the door was opened by a nurse. The officers identified themselves as FDA investigators, showed their credentials, and issued a notice of inspection (A-13). Upon asking to speak to Dr. Daley, the nurse refused to allow the officers to enter the reception area. The nurse advised the officers that Dr. Daley was not in the office that day and indicated that they would have to speak to the doctor's attorneys, Rothblatt, Seijas, and Peskin. See affidavit of Consumer Safety Officer John E. Klemmer (A-28-29).

In telephone conversations with plaintiff's attorney, Mr. Henry Rothblatt, subsequent to the first attempted inspection, FDA was advised that Dr. Daley does not use the drug Liefcort but does use a form of treatment conceived by the originator of the drug, Dr. Liefmann. Mr. Rothblatt also indicated that he had advised Dr. Daley to refuse to see FDA investigators. See affidavit of Supervisory Consumer Safety Officer, Terry B. Musson, para. 5 (A-23), and Consumer Safety Officer Allen R. Halper, para. 6 (A-26-27).

On February 28, 1975, the day following the second inspection, plaintiff brought this action seeking:

1. A declaration that FDA lacks authority and jurisdiction to investigate, inspect, or otherwise enforce the provisions of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 et seq. (the Act), against Dr. Daley for her conduct in preparing, prescribing, and administering approved drugs or combinations thereof to her own patients in the course of her medical practice.

2. An injunction restraining defendants from investigating, inspecting, or otherwise enforcing the provisions of the Act against Dr. Daley for her conduct in preparing, prescribing, and administering approved drugs or combinations thereof to her own patients in the course of her medical practice.

ARGUMENT

POINT I

There Is No Basis For Declaratory Judgment.

Dr. Daley contends [Br., p. 15][1] that there is a clearly defined controversy between the parties. But the only controversy plaintiff identifies is simply a disagreement as to the authority of FDA under 21 U.S.C. 374 to inspect the premises of a physician's office. This disagreement is not sufficient, as the district court concluded (A-61), to constitute a controversy ripe for adjudication.

In reaching this decision, the district court relied on the guidelines for pre-enforcement judicial review of final agency action established by the Supreme Court in *Abbott Laboratories* v. *Gardner*, 387 U.S. 136 (1967). As the district court noted, the test to be applied for ascertaining the appropriateness of judicial review of such action (A-55-56):

> . . . is twofold in nature and involves an evaluation of "both the fitness of the issues for judicial decision and the hardship to the parties of withholding court consideration." *Abbott*, *supra*, 387 U.S. at 149. The first part of the test, i.e., the fitness of the issues for resolution, itself consists of two parts—whether the issues raised were purely legal in nature and whether the challenged agency action was final. *Id.*

In applying the *Abbott* guidelines, it is clear that the district court limited its consideration to the actual agency action challenged and did not consider defendants' refusal to conduct a prearranged "inspection" of plain-

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[1] Reference to "Br." are to the brief for appellant.

tiff's office, as plaintiff offered after this action was instituted [Br., p. 16]. Thus, the district court pointed out that (A-57):

> In this case, the only action taken by FDA had been to cause two notices of inspection to be served and to question plaintiff's nurse. The notices merely recite various statutory provisions authorizing FDA inspections without specifying the purpose of the inspection or what FDA expects to find on the premises it seeks to enter. [Footnote omitted.]

A. The Issues Presented are Not Fit For Judicial Resolution.

In view of the limited scope of the agency action challenged, the district court's refusal to exercise jurisdiction was clearly in accord with the principles of *Abbott Laboratories* v. *Gardner*, *supra*. With respect to the fitness of the issues for judicial resolution, the district court concluded that (A-57):

> While the issue raised appears to be a purely legal one, *i.e.*, *the* FDA's statutory authority to inspect a physician's office, there is here no final agency action whose legality the court may pass upon.

Plaintiff contends [Br., p. 18] that the district court erred in ruling that this case presents no final agency action for review. In support of this contention, plaintiff argues that the Supreme Court in *Abbott Laboratories* v. *Gardner*, *supra* [387 U.S. at 149-152], applied a "pragmatic" and "flexible" test for the determination of the finality of agency action. But the regulation challenged there required ". . . an immediate and significant change in the plaintiffs' conduct of their affairs. . . ." *Abbott Laboratories* v. *Gardner*, *supra* [387 U.S. at 153].

The district court clearly recognized that the FDA action challenged here will have no immediate and significant effect on the plaintiff's conduct of her affairs when it found that (A-57):

> Although FDA agents made two visits to plaintiff's office, no inspection was in fact conducted. The court is reluctant to anticipate what future action, if any, FDA may decide to take.

In addition, the district court relied on this Court's ruling in *American Dietaids Co., Inc.* v. *Celebrezze*, 317 F.2d 658 (2d Cir. 1963), affirming the dismissal of an action brought to enjoin FDA inspectors from using concealed tape recorders during future inspections of the plaintiff's premises. In particular, the district court relied on this Court's declaration that (A-58):

> There is no ground in such a single past incident for declaratory relief against possible future inspections. There is no actual controversy now existing on which to found declaratory relief. . . . "Especially where governmental action is involved, courts should not intervene unless the need for equitable relief is clear, not remote or speculative." [Quoting from *Eccles* v. *People's Bank of Lakewood Village, Cal.*, 333 U.S. 426, 431.] 317 F.2d at 660.

Moreover, the district court recognized the significant distinction between the Agency action challenged in *Abbott Laboratories* v. *Gardner*, *supra*, and *Gardner* v. *Toilet Goods Ass'n.*, 387 U.S. 167 (1967), in stating that (A-58):

> In those cases the challenged regulations required the plaintiffs to take positive action which would have had "a direct effect on the[ir] day-to-day business. . . ." Here, no action on plaintiff's part is required—the ball, so to speak, is in FDA's court.

In attacking the district court's conclusion that this case presents no final Agency action for review, plaintiff cites no authority that supports her contention [Br., p. 18] that the district court misconstrued the Supreme Court's decision in *Abbott*. Each of the cases relied on by plaintiff involves agency action having a direct and immediate impact on the business activity of the plaintiff. *Aquavella* v. *Richardson*, 437 F.2d 397 (2d Cir. 1971), involved a suspension of Medicare payments to plaintiff's nursing home; an action which had an immediate and substantial impact on plaintiff's business activity. *National Automatic Laundry and Cleaning Council* v. *Schultz*, 443 F.2d 689 (C.A. D.C., 1971), held ripe for review "a ruling" by the Wage and Hour Administrator, responding to a letter, that coin operated laundries are subject to the Fair Labor Standards Act; an action also found to impose a direct effect on business activity. Similarly, *Independent Broker-Dealers' Trade Association* v. *SEC*, 442 F.2d 132 (C.A. D.C., 1971), held ripe for review an SEC "request" that resulted in the New York Stock Exchange abolishing customer directed "give-ups" of brokerage fees.

Consequently, it is not surprising that plaintiff attempts [Br., pp. 19-21] to inflate the FDA's action to make it seem more than simply the service of two notices of inspection and the questioning of plaintiff's nurse. See the district court's memorandum opinion at A-57. While defendants refused to agree to a pre-arranged "inspection" after this action was commenced and maintain that FDA is authorized by 21 U.S.C. 374(a) to inspect the premises of a physician's office, neither requires any immediate and significant change in plaintiff's conduct of her affairs.

Similarly, plaintiff's arguments [Br., pp. 12-14] concerning the identity of the drugs she uses and the extent to which a licensed physician may use an FDA approved

drug in an unapproved manner is not relevant to the Agency action challenged here. In any event, plaintiff's status as a physician does not exempt her from compliance with the law nor from reasonable and necessary administrative monitoring to assure compliance. See *United States* v. *Moore*, — U.S. —, 44 LW 4023 (December 9, 1975); *Defreese* v. *United States*, 270 F.2d 730 (5th Cir. 1959), *cert. den.*, 362 U.S. 944; *Brown* v. *United States*, 250 F.2d 745 (5th Cir. 1958), *cert. den.*, 356 U.S. 938.

B. There Is No Hardship To The Parties In Withholding Court Consideration.

Since the Agency action challenged here will have no immediate and significant effect on plaintiff's affairs, there is no hardship in withholding court consideration of that action. Although plaintiff contends [Br., p. 21] that she faces possible criminal prosecution for refusing these inspections, nothing in the record before the Court establishes more than a mere possibility that plaintiff may be subject to such a prosecution.

While plaintiff's brief at p. 21 states that "Plaintiff had twice refused to permit FDA inspections of her office", her affidavit (A-15) indicates only that her nurse was present at the time of the attempted inspections. There is no present indication whether plaintiff or an associate authorized or ordered the action taken by the nurse.[4] Plaintiff has made no showing in the record before the Court of any basis on which she may be threatened with criminal prosecution for refusal of inspection under 21 U.S.C. 331(f).

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[4] The affidavit of FDA official George J. Gerstenberg (A-30) indicates that plaintiff's office is shared with another physician. He was originally a plaintiff in this suit (Br., p. 5 n.2).

Although plaintiff relies [Br., p. 22] on *Gardner* v. *Toilet Goods Ass'n.*, *supra*, 387 U.S. at 171, this is not a case involving formally promulgated regulations which had "an immediate and substantial impact" on manufacturers' business activity and which clearly subjected the manufacturers to criminal sanctions if they failed to comply. Here, there is nothing more than a possibility that plaintiff could be prosecuted for refusing the two attempted inspections. It is no more than speculation that the FDA will attempt to conduct an inspection in the future, that the plaintiff will refuse to allow such inspection, and that the plaintiff will be prosecuted for such refusal. The "mere possibility" of criminal prosecution under these circumstances is not, as plaintiff contends [Br., p. 22], sufficient to warrant pre-enforcement review. As the district court concluded (A-60):

> [plaintiff's] fear of prosecution, however, is not a sufficient predicate for this Court to retain jurisdiction. Here, there is no indication that the government intends to prosecute plaintiff either for her past two refusals to permit entry or for any future refusals—unlike the situation in *Doe* v. *Bolton*, 410 U.S. 179 (1973) where physicians challenged the constitutionality of a Georgia abortion statute under whose predecessors doctors were actually prosecuted. . . .
>
> * * * * *
>
> . . . absent compelling circumstances, such as presented in the *Doe* case, there is no basis for a court to issue a judgment declaring in advance of a criminal prosecution that acts already committed or even to be committed in the future, are or are not unlawful. Cf. *Ewing* v. *Mytinger & Casselberry*, 339 U.S. 594, 599 (1950).

Even though plaintiff contends [Br., p. 23] that she has no means to challenge FDA's interpretation of 21

U.S.C. 374(a) without risking criminal sanctions,[5] that alone does not constitute the "compelling circumstances" which the district court concluded would be necessary to warrant entertaining such a challenge now. Beyond this suit reflecting plaintiff's disagreement with the Agency's interpretation of its statutory authority, there is nothing to establish that the Agency action challenged has had any impact on plaintiff. Compare the impact on business activity resulting from the regulations challenged in *Abbott Laboratories* v. *Gardner*, *supra*, and *Gardner* v. *Toilet Goods Association*, *supra*. Similarly, without final Agency action, even plaintiff's contention that a civil action would be "injurious to her reputation in the sensitive medical profession" [Br., p. 24] does not justify court consideration.

It is well-established that an application for declaratory judgment is addressed to the sound discretion of the Court. *Abbott Laboratories* v. *Gardner*, *supra* [387 U.S. at 148]; *Muller* v. *Olin Mathieson Chemical Corp.*, 404 F.2d 501, 505 (2d Cir. 1968); *Lebowich* v. *O'Connor*, 309 F.2d 111 (2d Cir. 1962). Because there has been no final Agency action by FDA, the district court's decision not to exercise its discretion to retain jurisdiction should be affirmed.

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[5] While the district court suggests (A-60-61) that plaintiff might defend such a prosecution on the ground of good faith non-compliance, this is contrary to the well-established principle that neither intent nor awareness of wrong-doing need be shown in criminal actions under the Federal Food, Drug, and Cosmetic Act. *United States* v. *Park*, 421 U.S. 658 (1975); *United States* v. *Dotterweich*, 320 U.S. 277 (1943).

POINT II

There Is No Basis For Injunctive Relief.

The Secretary, through New York District Regional Director Gerstenberg, Supervisory Consumer Safety Officer Musson, and Consumer Safety Officers Halper, Klemmer and Gardine, attempted on two occasions to conduct an inspection of plaintiff's premises in connection with a report that plaintiff had received the drug Liefcort after shipment in interstate commerce for use in the treatment of patients. Such regulatory inspections pursuant to 21 U.S.C. 372(a) and 374(a) of establishments where drugs are manufactured, processed, packed or held before or after shipment in interstate commerce, are predicated on the power of the United States to regulate interstate commerce. Statutes authorizing such regulatory inspections by the United States or by the States date from colonial days. *Golden Grain Macaroni Co., Inc.* v. *United States*, 209 F.2d 166 (9th Cir. 1953); *United States* v. *Crescent-Kelvan Co.*, 164 F.2d 582 (3d Cir. 1948); *United States* v. *75 Cases . . . Peanut Butter*, 146 F.2d 124 (4th Cir. 1944), *cert. den.*, 325 U.S. 856 (1945). Plaintiffs have not shown that they will suffer immediate and irreparable harm if injunctive relief is denied. Attempts to stay the hand of the FDA in similar situations have been unsuccessful.

In American Dietaids Co., Inc. v. *Celebrezze, supra* [215 F. Supp. 252 (S.D.N.Y.), aff'd. 317 F.2d 658 (2d Cir. 1963)], a food manufacturer discovered FDA inspectors carrying a concealed tape recorder during an inspection pursuant to 21 U.S.C. 374(a). The action was brought for a declaration that the acts of the inspectors were violative of the provisions of § 374(a) and of the Fourth Amendment's prohibition of illegal search and

seizure and seeking an injunction against such acts. The district court entered summary judgment dismissing the complaint on the grounds that declaratory judgment was an inappropriate remedy. In affirming the dismissal, the Court of Appeals for this Circuit pointed out [317 F.2d at 660] that:

> There is no ground in such a single past incident for declaratory relief against possible future inspections. There is no actual controversy now existing on which to found declaratory relief. [Treatise and cases cited omitted.]

A similar ruling was entered in *Durovic* v. *Palmer*, 342 F.2d 634 (7th Cir. 1965). There, FDA inspectors visited a drug manufacturing establishment on Saturday, took a photograph, and collected samples. Action was brought for an injunction requiring the discontinuance of such inspections on the grounds that the inspectors had exceeded their statutory authority thereby violating plaintiff's rights under the Fourth Amendment. Plaintiff there contended that the inspection had not been conducted at a "reasonable time" as required by 21 U.S.C. 374 on the asserted ground that the plant was not open for business on Saturday. The Court dismissed the action, however, on the ground that the inspection was not unreasonable since the plant was unlocked, the manufacturing process was underway, and sales transactions took place during the inspection. Furthermore, in affirming the dismissal, the Court of Appeals ruled [342 F.2d at 637] that plaintiff was not entitled to an injunction against further investigations because,

> . . . even assuming that the . . . inspection was illegal, there was no showing in the district court of continued or future inspections of such character or the threat thereof.

So here, there has been no showing that FDA will again attempt to inspect plaintiff's office. Indeed, the district court clearly indicated its reluctance ". . . to

anticipate what future action, if any, FDA may decide to take (A-57)." Accordingly, there is no factual basis in the record before the Court to justify the finding of irreparable injury that is necessary for the entry of injunctive relief.

POINT III

The Federal Food, Drug, And Cosmetic Act, 21 U.S.C. 374(a), Authorizes Inspection By The Food And Drug Administration Of The Premises Of A Physician's Office.

Should the Court find it necessary to reach this issue, FDA clearly has the authority under 21 U.S.C. 374(a) to conduct inspections of the premises of a physician's office as attempted here. The first sentence of 21 U.S.C. 374(a) provides in pertinent part that:

> For purposes of enforcement of this Act, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized (1) to enter, at reasonable times, any . . . establishment in which drugs . . . are manufactured, processed, packed, or held for introduction into interstate commerce or after such introduction . . . and (2) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such . . . establishment . . . and all pertinent equipment, finished and unfinished materials, containers, and labeling therein.

While 21 U.S.C. 374(a) (first sentence) applies to *drugs* generally, where *prescription drugs* are involved the Act provides *additional* and special authority. Thus, the second sentence of § 374(a) extends FDA's inspectional authority with respect to establishments in which *prescription drugs* are manufactured, processed, packed, or held:

> to all things therein (including records, files, papers, processes, controls, and facilities) bearing on whether prescription drugs . . . which may not be . . . introduced into interstate commerce . . . have been or are being . . . held in such place. . . .

Expressly exempted from the *second sentence* of § 374 (a) are "practitioners licensed by law to prescribe or administer drugs and who . . . prepare, propagate, compound, or process drugs solely for use in the course of their professional practice." 21 U.S.C. 374(a)(2). While plaintiff contends [Br., p. 14] that there is an express exemption for licensed practitioners from 21 U.S.C. 374, this is clearly contradicted by the statute itself. The first sentence authorizes inspection of an establishment in which *drugs* are held after shipment in interstate commerce. The second sentence provides *additional* inspectional authority with respect to an establishment in which *prescription drugs* are manufactured or held after shipment in interstate commerce. 21 U.S.C. 374(a)(2) exempts licensed practitioners from the scope of inspection authorized by the second sentence, but no such exemption is provided from the general inspectional authority of the first sentence of the statutory provision.

The provisions of the first and second sentences of 21 U.S.C. 374(a) are not mutually exclusive. The first sentence provides general authority to inspect establishments in which drugs, including prescription drugs,[6] are manufactured or held. Among other things, the first sentence provides for entry, the presentation of credentials and notice, and requires that the inspection be conducted at reasonable times, within reasonable limits, and in a rea-

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[6] The term *drug*, as defined by 21 U.S.C. 321(g)(1), includes drugs which must be dispensed on prescription pursuant to 21 U.S.C. 353(b). See *Defreese* v. *United States*, 270 F.2d 730 (5th Cir. 1959).

sonable manner. These provisions are not duplicated by the second sentence of § 374(a).

Both the first and second sentences of 21 U.S.C. 374 (a) apply to *establishments* in which drugs [prescription drugs] are manufactured, processed, packed, or held. It is clear that Congress clearly recognized that without the exempting provision, 21 U.S.C. 374(a)(2), the provisions of the second sentence of § 374(a) would have applied to licensed practitioners; otherwise the exemption would be surplusage. It is equally clear that Congress did not intend the exemption of 21 U.S.C. 374(a)(2) to impose any limitation on the scope of the *first* sentence of § 374 (a), since the specific provisions relating to inspectional authority with respect to prescription drugs added by the Drug Amendments of 1962, Pub. L. No. 87-781, Title II § 201(a) (October 10, 1962), 76 Stat. 792, were not intended "to detract from or imply the absence of existing authority as to other drugs . . . subject to the Act. S. Rep. No. 1744, 1962 U.S. Code, Cong. and Admin. News 2889. Accordingly, plaintiff's premises are subject to the *general* inspectional authority of 21 U.S.C. 374(a) (first sentence), as an establishment where *drugs* are manufactured, processed, packed, or held after shipment in interstate commerce.[7]

Plaintiff's suggestion [Br., p. 14] that 21 U.S.C. 374 is limited to "factory inspection" has long been rejected and the "comprehensiveness of the statute" recognized. *United States* v. *Herold*, 136 F. Supp. 15, 16 (E.D., N.Y., 1955). 21 U.S.C. 374(a) speaks in terms of "any . . . establishment in which . . . drugs . . . are held." Accordingly, it must be concluded that the term "establishment"

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[7] Plaintiff does not contend that the drugs which are on the premises of her office for the treatment of patients have not been shipped in interstate commerce. See amended complaint (A-4); plaintiff's affidavit (A-16).

as used in the first sentence of § 374(a) includes the premises of a licensed practitioner and that the first sentence of 21 U.S.C. 374(a) authorizes FDA inspections of the type attempted here.

Furthermore, a warrantless, administrative inspection of plaintiff's office would not violate the Fourth Amendment. Plaintiff's contention [Br., pp. 14-15] is premised on a lack of statutory authority, although this position ignores the plain meaning of 21 U.S.C. 374(a) as explained above. An neither of the cases relied on by plaintiff support its contention. *Colonnade Catering Corp.* v. *United States*, 397 U.S. 72 (1970), held that the statute authorizing Treasury agents to enter and inspect a liquor licensee's premises without a warrant and making the refusal to allow entry a criminal offense does not authorize forcible entry without a warrant when entry is denied by the licensee. *United States* v. *Biswell*, 406 U.S. 311 (1972), involved the legality of a warrantless search of a locked storeroom as part of the inspection procedure authorized by the Gun Control Act of 1968 which resulted in the seizure of unlicensed firearms from a dealer licensed to deal in sporting arms. The dealer had acquiesced to the search upon being advised by the investigator that no warrant for the search had been issued but that the statute authorized such inspections. The Supreme Court held that the dealer's acquiescence to the search did not violate any of his constitutional rights, since the legality of the search did not depend on the dealer's consent but on the authority of the statute.

Applying the holding in *United States* v. *Biswell*, *supra*, it has been held that warrantless administrative inspections conducted pursuant to 21 U.S.C. 374(a) were not violative of the Fourth Amendment whether or not the defendant knowingly consented to the inspection. *United States* v. *Del Campo Baking Mfg. Co.*, 345 F. Supp. 1371 (D. Del., 1972); *United States* v. *Business Builders, Inc.*, 354 F. Supp. 141 (N.D. Okla., 1973).

CONCLUSION

On the basis of the foregoing, it is respectfully submitted that the judgment appealed from should be affirmed.

Dated: Brooklyn, New York
March 15, 1976

Respectfully submitted,

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AFFIDAVIT OF MAILING

STATE OF NEW YORK
COUNTY OF KINGS
EASTERN DISTRICT OF NEW YORK, ss:

EVELYN COHEN, being duly sworn, says that on the 15th day of March, 1976, I deposited in Mail Chute Drop for mailing in the U.S. Courthouse, Cadman Plaza East, Borough of Brooklyn, County of Kings, City and State of New York, a BRIEF FOR THE APPELLEE of which the annexed is a true copy, contained in a securely enclosed postpaid wrapper directed to the person hereinafter named, at the place and address stated below:

Rothblatt, Rothblatt, Seijas & Peskin
232 West End Avenue
New York, N.Y. 10023

Evelyn Cohen

Sworn to before me this
15th day of March, 1976

Olga S. Morgan

OLGA S. MORGAN
Notary Public, State of New York
No. 24-4501966
Qualified in Kings County
Commission Expires March 30, 1977